REMARKS

Reconsideration of the present application as amended is hereby requested. This continuation application included claims 98-173 which were added by preliminary amendment. To reduce the issues to be addressed with this response, Applicants have cancelled claims 126-173 directed to an apparatus and a kit, without prejudice to consideration in a continuing application. Each of the remaining claims 98-125 stand rejected on various grounds.

The pending claims were rejected under 35 U.S.C. 112, first paragraph on the grounds that the claims recite subject matter that is not adequately described in the specification. In particular, it was suggested that the specification failed to adequately disclose accessing the space under the tibial plateau (in claims 98 and 108) and stacking wafers in the general direction of the axis of the tibia (found in claims 99 and 108). Treatment of a tibial plateau compression fracture is disclosed at page 27 of the specification. The nature of this type of compression fracture is well-known in the art. The specification describes providing a "pathway to the underside of the depression" (lines 15-17), which is the situs of the compression fracture of a tibial condyle. It is readily understood that this "pathway" must necessarily occur in a space under the tibial plateau. Thus, the language in claims 98 and 108 of "accessing the space under the tibial plateau" is supported by the cited excerpt. With respect to the language in claims 99 and 108 regarding the "direction of the axis of the tibia", it is again known that any reduction of a tibial plateau compression fracture must necessarily occur generally along the axis of the tibia so that the reduced plateau will be restored to its normal anatomic orientation. Distracting in any other direction will result in the affected condyle being improperly aligned, which will compromise the knee joint. The specification describes placing the wafers in a vertical column "until the articular surface is reduced", which is in accordance with known orthopaedic techniques. Any person of ordinary skill in this art would understand the claims of this application, and more specifically would understand the limitations regarding the "space under the tibial plateau" and the "direction of the axis of the tibia." Thus, it is believed that the claims of the present application are fully and adequately supported by the specification.

Claims 126-168 were rejected under 35 U.S.C. 101. These claims have been cancelled in this response, so the rejection is moot.

All of the pending claims were rejected for obviousness-type double patenting based on Applicants' issued patent No. 6,595,998 in view of the patent to Reiley et al. 6,066,154.

Applicants will provide an appropriate Terminal Disclaimer if necessary when the pending claims are in condition for allowance.

Anticipation rejections were issued against the apparatus and kit claims. Since these claims have been cancelled, those rejections are moot.

Of the remaining method claims, claims 98-103, 105 and 106 were rejected as obvious in view of the combination of the patent to Baumgartner with the Reiley patent. Baumgartner discloses introducing a multiplicity of elastic members to fill a cavity within the intervertebral space. The members emulate the natural elasticity of the intervertebral disc nucleus that the Baumgartner members are intended to replace. Thus, for purposes of the Baumgartner invention, it is critical that the members be formed of an elastic material. Baumgartner neither discloses nor contemplates introducing a rig or inelastic member into the space. Moreover, Baumgartner neither discloses nor contemplates using an inserted member to distract opposed surfaces as the member is inserted.

As originally written, method claim 98 recited consecutively introducing a plurality of elements to distract and support opposing surfaces of the tibia. While it is believed that this language is sufficient to distinguish over the elastic elements of Baumgartner, Applicants have amended claim 98 to define the introduced elements as "substantially rigid" and to make clear that the action of distracting the opposing surfaces occurs as the elements are consecutively received. Support for this language is found in the third full paragraph on page 12 of the specification. The Baumgartner elements must be elastic and are therefore not substantially rigid. Moreover, the Baumgartner elements are not used to distract the disc space into which the elements are inserted. The Reiley patent does not overcome this deficiency in Baumgartner, since Reiley simply discloses an inflatable (and therefore not rigid) balloon. It is therefore believed that claim 98 as amended is patentable over Baumgartner alone or in combination with the Reiley reference. Thus, the rejection of claims 98-103, 105 and 106 in view of Baumgartner with Reiley has been traversed.

Pending method claims 98-104, 107-112, 117-119, 121, 124 and 125 were rejected as obvious in view of the combination of Brantigan with the Reiley patent. The Brantigan patent discloses replacement bodies for the spine. However, the Brantigan bodies are not configured for or disclosed as being consecutively introduced into a tissue space, as required by independent method claim 108. Even if the Brantigan replacement bodies support distracted surfaces, they

are not configured to cause the distraction as each body is inserted. Moreover, even where multiple bodies are combined in Brantigan, they are combined prior to insertion into the spine.

While claim 108 originally recited that the stacking of the elements would generate the distraction, Applicants have amended claim 108 to more clearly point out that the distraction occurs as each wafer is individually inserted. Brantigan does not disclose individual insertion of a plurality of the replacement bodies. Instead, Brantigan contemplates that the vertebral space is separately distracted and held until the stack of replacement bodies has been introduced into the space.

As acknowledged in the Office Action, Brantigan does not disclose introducing the replacement bodies to treat a tibial plateau compression fracture. The Reiley patent was cited because it discloses the use of an inflatable balloon in various orthopaedic applications, including treatment of the spine and of the tibial plateau. However, the balloon in Reiley is intended to compress cancellous bone as the balloon is expanded. Reiley does not disclose distraction of tissue surfaces, nor is the Reiley balloon capable of independently maintaining compression fracture surfaces or of supporting the tibial plateau. At best, Reiley discloses that compressing cancellous bone can occur in a variety of bones, such as the tibia and vertebral body. Simply because Reiley refers to different orthopaedic procedures does not mean that it suggests the desirability of implementing every form of spinal procedure in treatment of a tibial plateau compression fracture.

The Brantigan patent discloses annular plugs that require significant resection of material in order to be received within a bony structure. In order to adapt a Brantigan annular plug to the tibia, it would be necessary to resect a significant portion of the proximal end of the tibia. However, this extensive bone resection would defeat the purpose of Applicants' invention, namely to restore the tibia to its original anatomy. The consecutive individual insertion of Applicants' wafer allows a small opening to be formed in the tibia, thereby preserving the natural anatomy of the tibia. The Brantigan annular plug is directly contrary to this goal of Applicants' invention. The Reiley patent's discussion of the tibial plateau does not add anything to suggest the viability of placing a Brantigan implant in the tibia and certainly does not overcome the significant problems associated with introducing a Brantigan implant into the tibia.

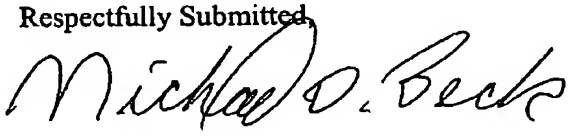
Even if the Brantigan plug and procedure can be somehow adapted for treatment of tibial plateau compression fractures, the annular plugs cannot be considered to be configured for consecutive insertion and for distracting the tissue surfaces as each element is consecutively

inserted. The annular plugs in the Brantigan '327 Patent exhibit no characteristics that could allow any plug to be jammed between tissue surfaces or between plugs already in position. Although the term "distraction" is not expressly mentioned in the Brantigan '327 Patent, it is indicated that the disc annulus is stretched so that the vertebrae can engage a disc replacement plug. (Col. 2, lines 59-66). Brantigan further states that, "During surgery, the spinal column is stretched to regain any lost disc space ...", and that, "This stretches the remaining disc tissue and ... the plugs ... are inserted into the opened up disc space ... while mounted on a tool ...". (Col. 6, lines 59-65). Figures 13 and 14 of Brantigan also depict the disc space as being distracted enough to permit direct insertion of the plug 11. Thus, it can be appreciated that in the absence of any pre-distraction of the space the ridges on the surfaces of the plug would necessarily dig into the vertebral bodies. This action directly contradicts one of the expressed purposes of the plug in Brantigan, namely to mount the plugs without penetration through the hard faces of the vertebrae. Col. 7, lines 23-25.

Thus, it is apparent that Brantigan does not contemplate that the plugs 11 would be capable of distracting tissue surfaces as the plugs are consecutively inserted, as required by Applicants' claims. While it is true that both the Brantigan plugs and Applicants' claimed elements can maintain distraction once the construct is complete, only Applicants' claimed invention is configured to actively distract while each element is inserted. Again, the structure of the Brantigan plugs makes it clear that space for insertion of the plugs must already be available, otherwise the plug will just butt up against the vertebral bodies or a plug already in position.

In view of the foregoing arguments and amendments, it is believed that all of the pending claims 98-125 are allowable over the art of record. Action toward a Notice of Allowance is earnestly requested.

Respectfully Submitted,



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